UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,734	07/28/2003	Jon A. Wolff	Mirus.013.03.6	5547

25032 7590 04/17/2006

MIRUS CORPORATION
505 SOUTH ROSA RD
MADISON, WI 53719

EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,734	WOLFF ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *6-8,19-21,28 and 36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 9-18, 22-27, 29-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed July 28, 2003, is a CIP of 09/447,966, filed 11/23/1999, now US PAT 6,627,616.

Claims 1-38 are pending.

Election/Restrictions

Applicant's election of Group I in the reply filed on February 7, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

With respect to the species election, Applicants elect the species of VEGF and skeletal muscle. Initially, Examiner agrees with Applicants that the species recited in claim 5 are obvious variants of vascular endothelial cell growth factor, and is a well defined sub-genus of numerous characterized angiogenic factors known in the art at the time of filing. Accordingly, the restriction requirement is withdrawn to the extent it required a specific species of vascular endothelial cell growth factor recited in claim 5 to be elected. No arguments are provided for the species of muscle.

Claims 1-38 are pending. Claims 6-8, 19-21, 28, 36-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the

restriction (election) requirement in the reply filed on February 7, 2006. Claims 1-5, 9-18, 22-27, 29-35 are currently under consideration as they are drawn to a process for delivering an angiogenic protein or peptide wherein it is a vascular endothelial growth factor (sub genus of claim 4) to a skeletal muscle to enhance blood flow, comprising administering a naked polynucleotide to a blood vessel, increasing the pressure in and delivering the nucleic acid to the skeletal muscle

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/447,966, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Accordingly, the priority date given the instant application is it's filing date of July 28, 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 7, 2004 and May 21, 2004 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

It is noted that the IDS submitted May 21, 2004 has been signed but lined through because the references listed are duplicated in the August 7, 2004 submission. The August 7, 2004 submission was used because it was the most comprehensive listing all the references to be considered.

Claim Objections

Claims 1-3 and 35 are objected to because of the following informalities:

The elected invention is drawn to are currently under consideration as they are drawn to a process for delivering an angiogenic protein or peptide wherein it is a vascular endothelial

growth factor (sub genus of claim 4) to a skeletal muscle to enhance blood flow, comprising administering a naked polynucleotide to a blood vessel, increasing the pressure in and delivering the nucleic acid to the skeletal muscle, however the claims as pending encompass a much broader scope.

Appropriate correction is required.

Claims 2-5, 13, 14, 22, 30, 31-34 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

In this case, it appears that the claims simply set forth inherent properties or effects that would be affected in practicing the method from which they depend.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 9-18, 22-27, 29-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically;

Claims 1 and 35 are vague and confusing and appear in part to be incomplete. The pre-amble of the claims requires a method that results in improved or enhanced blood flow, however the methods only end in the polynucleotide being expressed (claim 1) or simply delivered (claim

35). It is unclear if this is to be an inherent property of practicing the method or if other steps are required to complete the intent of the invention. Dependent claims are included in the basis of the rejection because they fail to clarify the basis of the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 9-18, 22-27, 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isner (US Patent 6,121,246) in view of Milas *et al.*, Von Der Leyen *et al.* and Budker *et al.* (each listed in the IDS).

The invention encompasses a process for delivering an angiogenic protein or peptide wherein the angiogenic protein is a vascular endothelial growth factor to a skeletal muscle to enhance blood flow, comprising administering a naked polynucleotide to a blood vessel that encodes an angiogenic protein, increasing the pressure in and delivering the nucleic acid to the

skeletal muscle. At the time of filing gene therapy methods for the treatment of ischemic tissue were known and practiced. Isner discloses gene therapy methods where a polynucleotide encoding a angiogenic factor are delivered to ischemic muscle tissue. More specifically, Isner discloses the delivery of a polynucleotide encoding various species of VEGF ($VEGF_{165}$ in EXAMPLE 1 for example) to the muscle of a subject to induce angiogenesis. Upon analysis it was found that the treatment resulted in new capillary formation as expected (see column 8 for example). Isner discusses the general use of the method for a variety of circumstances in which ischemic tissue results, including results of disorders, disease or damage (see column 2 for example or summary in abstract). Isner discloses that a variety of methods for delivery are known and can be used, and would depend in particular on the specific requirements of treatment (starting at the bottom of column 5 for determining effective amount, and more generally throughout columns 1-6) Isner discloses a variety of methods for delivery, including the delivery and expression in a vessel, however fails to specifically teach a delivery method to the muscle by increasing the extracellular volume during delivery. At the time of filing, each Milas *et al.*, Von Der Leyen *et al.* and Budker *et al.* provide methodology and working examples where pressure mediated delivery was used to deliver DNA muscle, and the demonstration that expression of the DNA was accomplished (Milas *et al.* and Budker *et al.*).

Isner teaches a variety of methods for delivery and how they would be dependent on what was being treated, and in particular the problems of delivery through a vessel with a catheter. Milas *et al.*, Von Der Leyen *et al.* and Budker *et al.* each provide a teaching that the methods disclosed worked and have clinical merit, therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of

Milas *et al.*, Von Der Leyen *et al.* and Budker *et al.* for methods of delivery of a polynucleotide to a subject in conjunction with the teaching of Isner to more effectively deliver and affect angiogenesis in a subject in need thereof. One having ordinary skill in the art would have been motivated to use the methods of Milas *et al.*, Von Der Leyen *et al.* and Budker *et al.* for delivery to the muscle. Based on their own results Von Der Leyen *et al.* specifically proposes the use of the methodology for the vascular gene therapy (page 2363). Based on the results of Isner there would have been a reasonable expectation of success that VEGF would induce angiogenesis, and that the methods of Milas *et al.*, Von Der Leyen *et al.* and Budker *et al.* would be effective in the delivery of a polynucleotide to muscle.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

AU 1632